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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rena Nishizawa

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EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,596	Applicant(s) NISHIZAWA, RENA	
	Examiner JEFFREY H. MURRAY	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-10,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 4,7-10, and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1, 4, 7-10, 19 and 21 are pending in this application. Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 9, 2007. Claims 2, 3, 5, 6, 11-18 and 20 have been cancelled. This action is in response to the applicants' amendment after a non-final action and reply filed on March 12, 2008.

Status of Rejections

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph for failing to overcome the written description requirement. The applicants' arguments are noted, but found unpersuasive. The rejection of Claim 1 is hereby maintained.

3. Claims 1, 4, 7-10, and 21 are rejected under 35 U.S.C. 112, first paragraph as failing to overcome the enablement requirement. The rejection of Claims 1, 4, 7-10 and 21 is hereby withdrawn in view of applicant's amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

New/Maintained Rejections

4. Claim 1 continues to be rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement of the invention.

Applicants argue that examiner has "no legal basis" for the assertion that negative limitations within a claim are not permitted unless the proviso is described

within the specification as well. Examiner disagrees. Examiner points to MPEP 2173.05(i) which applicants themselves have also cited. "Any negative limitation or exclusionary proviso must have basis in the original disclosure." Examiner notes that nowhere in the original disclosure is there any basis or comment regarding these specific compounds or why these specific compounds would be excluded from the claim. These compounds are already known in the prior art. Applicants did not attempt to use a negative limitation until such time as they were made aware of these prior art compounds. MPEP 2173.05(i) states, "Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement."

Applicants have also argued that by claiming the whole (i.e. all of the species of formula (I) as recited in claim 1 prior to the amendment adding the limitation), that necessarily describes the part remaining (i.e., the more limited species defined by present claim 1 with the proviso.) Examiner also disagrees with this argument. Examiner points to the case of *Ex Parte Grasselli*, 231 USPQ 393 which discusses negative limitations which were not present in the original specification. The court finds the following:

Despite appellants' arguments to the contrary, we agree with the examiner's position of record that the negative limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973). The examiner's distinctions between the present case and the prior decisions cited by appellants are correct and we adopt his position in that regard as our own. It might be added that the express exclusion of certain elements implies the permissible inclusion of all other

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elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.

This decision states clearly that where the negative limitation did not exist in the specification and is subsequently added by amendment, it constitutes new concepts (aka "new matter") and must be rejected under U.S.C. 112, first paragraph for lack of a written description.

Allowable Subject Matter

5. Claims 4, 7-10 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4, 7-10 and 21 are free of the prior art. The closest prior art to the current claims is Teranishi, et. al., EP 70171, which teaches spiro-piperidine derivatives but does not teach the specific substituents of the present application.

Conclusion

6. Claim 1 is rejected.

7. Claims 4, 7-10 and 21 are objected.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner
Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624**